

Message Text

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ORIGIN ABF-01

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P 312200Z MAY 78
FM SECSTATE WASHDC
TO AMCONSUL FRANKFURT PRIORITY
AMEMBASSY OSLO PRIORITY
AMEMBASSY STOCKHOLM PRIORITY
AMEMBASSY BONN PRIORITY
AMCONSUL AMSTERDAM PRIORITY
AMEMBASSY THE HAGUE PRIORITY
USMISSION USBERLIN

UNCLAS STATE 138030

FRANKFURT FOR GAO EDER

E.O. 11652: N/A

TAGS: AGAO, ECSM

SUBJECT: GAO REVIEW: "NEW DRUG DEVELOPMENT AND APPROVAL
PROCESS"

1. THE GAO HAS INFORMED THE DEPARTMENT THAT IT PLANS TO UNDERTAKE SUBJECT REVIEW IN ADDRESSEE COUNTRIES IN PURSUANCE OF A CONGRESSIONAL REQUEST. DATES OF VISIT SUBJECT TO POST'S CONCURRENCE.
2. THE GAO WANTS TO COMPARE THE REQUIREMENTS, POLICIES,
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AND PRACTICES USED BY OTHER COUNTRIES TO REGULATE NEW DRUG DEVELOPMENT TO DETERMINE WHETHER NEW DRUGS ARE INTRODUCED MORE RAPIDLY THAN IN THE U.S. A SIGNIFICANT PORTION OF THIS WORK WILL ENTAIL A COMPARISON OF THE UNITED STATES' DRUG REGULATORY PROCESS WITH THE REGULATORY PROCESSES OF CERTAIN EUROPEAN COUNTRIES. THE GAO HAS JUST COMPLETED A REVIEW OF AND DEVELOPED INFORMA-

TION ON THE CANADIAN DRUG APPROVAL SYSTEM.

3. THE BASIC GAO OBJECTIVES IN THIS REVIEW WILL BE TO OBTAIN INFORMATION ON THE RELATIONSHIP BETWEEN THE HOST COUNTRY'S LEGISLATIVE BODY AND ITS DRUG REGULATORY AGENCY; THE LEGAL REQUIREMENTS FOR NEW DRUG APPROVALS AND THEIR IMPLEMENTING PROCEDURES, AND THE ADVANTAGES, IF ANY, OF FOREIGN DRUG APPROVAL PROCESSES OVER THOSE OF THE UNITED STATES. THE GAO ALSO PLANS TO OBTAIN THE OPINIONS OF FOREIGN REGULATORY AND PHARMACEUTICAL OFFICIALS, MEDICAL EXPERTS AND MEMBERS OF MEDICAL ASSOCIATIONS CONCERNING IMPROVEMENTS THAT COULD BE MADE TO THE DRUG APPROVAL PROCESS. THE GAO WILL ALSO BE INTERESTED IN SECURING INFORMATION ON THEIR RATE OF NEW DRUG DEVELOPMENT, THE COMPOSITION OF THEIR WORKLOAD AND PRIORITY SYSTEMS, THE LENGTH OF TIME REQUIRED FOR DRUG APPROVAL, THERAPEUTICALLY IMPORTANT DRUGS AVAILABLE OVERSEAS BUT NOT IN THE UNITED STATES, AND INCIDENCE OF ADVERSE REACTIONS AND DRUG RECALLS.

4. THE GAO WOULD APPRECIATE ADDRESSEE POSTS INFORMING REGULATORY OFFICIALS WHO ARE THE EQUIVALENT OF THE U.S. FOOD AND DRUG ADMINISTRATION'S DIRECTOR OF BUREAU OF DRUGS OF THIS REVIEW AND PLANNED VISIT. AFTER CONTACTING THESE REGULATORY OFFICIALS, PLEASE FORWARD TO DEPARTMENT THEIR NAMES AND TELEPHONE NUMBERS SO THAT GAO WASHINGTON UNCLASSIFIED

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CAN MAKE FOLLOWING CONTACTS TO WORK OUT DETAILS OF THE VISIT. IN EUROPE, AS WAS THE CASE IN CANADA, THE GAO'S PRINCIPAL OBJECTIVE WILL BE TO BRIEFLY MEET WITH SENIOR REGULATORY OFFICIALS TO OBTAIN AN OVERVIEW OF THEIR SYSTEM AND SPEND THE MAJOR PART OF THE TIME WITH THE PERSONNEL INVOLVED IN THE DAY-TO-DAY OPERATIONS OF THE DRUG APPROVAL PROCESS AS WELL AS WITH MEMBERS OF THE MEDICAL PROFESSION.

5. THE POST'S ASSISTANCE IS ALSO REQUESTED TO DESIGNATE AND INFORM DEPARTMENT THE NAME AND TELEPHONE NUMBER OF PROJECT OFFICER WHO WILL WORK WITH THE GAO TEAM IN SETTING UP MEETINGS WITH APPROPRIATE GOVERNMENT OFFICIALS AND REPRESENTATIVES OF BUSINESS FIRMS IN ACCORDANCE WITH THE DATES AVAILABLE FOR MEETINGS SHOWN IN PARAGRAPH 6. THE FOLLOWING FOREIGN OFFICIALS HAVE BEEN IDENTIFIED TO THE GAO AS POSSIBLE CONTACTS:

NORWAY

STATENS LEGEMIDDELKONTROLL
BOX 3299

SAGENE
OSLO 4, NORWAY

SWEDEN

PROFESSOR AKE LILIJESTRAND
DEPARTMENT OF DRUGS
NATIONAL BOARD OF HEALTH AND WELFARE
BOX 607
75125 UPPSALA, SWEDEN

SWEDEN

DR. HOLGAR LUNDEBECK
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DIRECTOR, NATIONAL INSTITUTE OF HEALTH
STOCKHOLM, SWEDEN

NETHERLANDS

MR. J. A. BRUNINGS
HOOFDAFDELING GENEESMIDDELEN,
MEDISCHE HULPMIDDELEN EN INFECTIECIEKTEN

CONTACTS WITH PHARMACEUTICAL ASSOCIATIONS AND PRIVATE
MEDICAL GROUPS WILL BE ARRANGED BY THE GAO THROUGH THE
PHARMACEUTICAL MANUFACTURERS ASSOCIATION IN THE
UNITED STATES.

FOR GENEVA: THE MISSION'S ASSISTANCE IN WORKING UP A
SCHEDULE FOR DR. MURRAY GRANT AND MESSRS. LAURIE AND
JOJOKIAN TO MEET WITH THE FOLLOWING NAMED PERSONNEL OF
THE WORLD HEALTH ORGANIZATION ON EITHER JULY 17 OR 18 WILL
BE APPRECIATED.

DR. V. FATTURUSSO, DIRECTOR, DIVISION OF PROPHYLACTIC,
DIAGNOSTIC AND THERAPEUTIC SUBSTANCES

DR. CHEN WEN-CHIEN, ASSISTANT DIRECTOR, (SAME DIVISION)

DR. FRANK PERKINS, DIRECTOR, BIOLOGICAL UNIT

6. THE GAO PLANS TO HAVE TWO TEAMS CONSISTING OF TWO
PERSONS TO CONDUCT THE REVIEWS IN EUROPE; TWO FROM THE
UNITED STATES AND TWO FROM THE GAO EUROPEAN BRANCH OFFICE
IN FRANKFURT. EACH TEAM WILL SPEND BETWEEN 2 AND 7 DAYS
IN EACH COUNTRY DURING THE 5-WEEK PERIOD FROM JUNE 26 TO
JULY 28, 1978 IN ACCORDANCE WITH THE SCHEDULE BELOW:
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TEAM NO. 2 LEAD BY MR. MILAN HUDAK PLUS ONE OTHER TEAM
MEMBER TO BE NAMED.

DATES AVAILABLE

DATES	COUNTRY	FOR MEETINGS
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JUNE 25	ARRIVE FRANKFURT	
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JUNE 26-28	FRANKFURT	
(WITH GAO)		

- DATES AVAILABLE

DATES	COUNTRY	FOR MEETINGS
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JUNE 28	ARRIVE OSLO BY AIR	
(P.M.)		

JUNE 29-30	NORWAY	JUNE 29-30
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JULY 1	ARRIVE STOCKHOLM	
(P.M.)		

JULY 2-8	SWEDEN	JULY 3-7
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JULY 9	ARRIVE AMSTERDAM	
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JULY 9-11	AMSTERDAM	JULY 10-11
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JULY 11	ARRIVE FRANKFURT	
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JULY 12-15	FRANKFURT	
(WITH GAO)		

JULY 15	ARRIVE AMSTERDAM	
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JULY 16-19	AMSTERDAM	JULY 17-19
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JULY 20	TRAVEL BONN	
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JULY 21-25	BONN	JULY 21-25
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JULY 25	TRAVEL FRANKFURT	
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(P.M.)

JULY 26-28 FRANKFURT
(WITH GAO)

7. IN ADDITION TO THE TWO-MAN TEAMS MENTIONED IN PARA 6
SUPRA, THE FOLLOWING GAO REPRESENTATIVES WILL TRAVEL ON
SEPARATE ITINERARY AND PARTICIPATE IN SOME OF THE VISITS
AS OUTLINED BELOW:

A) DR. MURRAY GRANT, MEDICAL ADVISOR, GAO/WASHINGTON,
WILL BE MEETING WITH MEDICAL EXPERTS AND MEMBERS OF
CONCERNED ASSOCIATIONS:

DATES	COUNTRY
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JUNE 26-28	FRANKFURT (WITH GAO)
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DATES	COUNTRY
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JUNE 29	DRIVING TO NORWAY
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JUNE 30	NORWAY
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JULY 3-4	SWEDEN BY AIR
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JULY 5	ARRIVE LONDON
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JULY 5-7	LONDON
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JULY 8	ARRIVE BY AIR SWEDEN
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JULY 10-11	AMSTERDAM
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JULY 12-14	FRANKFURT, GERMANY
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JULY 17-18	GENEVA (WHO)
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JULY 19-21	BERLIN
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JULY 24-25	BONN
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JULY 26-28	FRANKFURT (WITH GAO)
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B) MR. WILLIAM LAURIE, AUDIT MANAGER, GAO/DETROIT
REGIONAL OFFICE

JULY 9	ARRIVE LONDON
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JULY 10-11 ENGLAND

JULY 11 ARRIVE FRANKFURT

JULY 12-15 FRANKFURT (WITH GAO)

JULY 16 ARRIVE GENEVA

JULY 17-18 GENEVA (WHO)

JULY 19-22 ARRIVE BERLIN

JULY 23-25 BONN

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JULY 26-28 FRANKFURT (WITH GAO)

C) MR. ALBERT B. JOJOKIAN, ASSISTANT DIRECTOR, HUMAN
RESOURCES DIVISION, GAO/WASHINGTON

DATES COUNTRY

JULY 11 ARRIVE FRANKFURT

JULY 12-15 FRANKFURT (WITH GAO)

JULY 16 ARRIVE BERN

JULY 16-21 BERN

JULY 22 ARRIVE ROME (P.M.)

JULY 22-25 ITALY

JULY 25 ARRIVE BY AIR FRANKFURT (P.M.)

JULY 26-28 FRANKFURT (WITH GAO)

8. EXCEPT FRANKFURT, WHERE GAO REGIONAL OFFICE WILL
HANDLE HOTEL REQUIREMENTS, THE GAO WOULD APPRECIATE EACH
POST RESERVING HOTEL ACCOMMODATIONS AT REASONABLY
PRICED HOTEL IN ACCORDANCE WITH THE ITINERARIES LISTED
IN PARAGRAPHS 6 AND SUB-PARAGRAPHS B) AND C) OF PARA 7.
DR. GRANT WILL MAKE HIS OWN HOTEL ARRANGEMENTS.
PLEASE CONFIRM RESERVATIONS TO THE DEPARTMENT AND INFO
FRANKFURT FOR GAO.

9. NAMES OF REMAINING TEAM MEMBERS AND SECURITY
CLEARANCE AS WELL AS TRAVEL SCHEDULES WILL BE PROVIDED BY
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SEPTTEL FROM GAO FRANKFURT. GAO REPRESENTATIVES WILL MAKE THEIR OWN LOCAL TRANSPORTATION ARRANGEMENTS.

10. DEPARTMENT CERTIFIES THAT MESSRS. VIEREGGE, HUDAK, LAURIE AND JOJOKIAN GAO PERSONNEL HOLD CURRENT TOP SECRET SECURITY CLEARANCE. DR. GRANT HAS A SECRET CLEARANCE.

11. THE GAO IS AWARE THAT CONTACTS WITH FOREIGN OFFICIALS ARE AT THE DISCRETION OF THE AMBASSADOR, TO BE ARRANGED FOR BY THE EMBASSY AND EMBOFF TO ACCOMPANY, IF FEASIBLE.

12. GAO TEAM MEMBERS WILL BE PLEASE TO BRIEF THE AMBASSADOR OR APPROPRIATE EMBASSY OFFICER ON THE RESULTS OF VISITS, IF DESIRED. PLEASE ADVISE.

13. DEPARTMENT WISHES TO COOPERATE WITH THE GAO IN ACCORDANCE WITH 4 FAM 930-934. ANY QUESTIONS OR PROBLEMS THAT ARISE DURING THE COURSE OF THE REVIEW SHOULD BE REFERRED TO THE DEPARTMENT. CHRISTOPHER

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